

AMENDMENTS TO THE DRAWINGS

Attached are three sheets of replacement Figures 1-8 for Figures 1-8 as originally filed.

Attachment: Replacement Sheets (3)

REMARKS/ARGUMENTS

Claims 25-35 and 37-52 are pending. By this Amendment, the Abstract and claims 25, 29, 32, 37 and 38 are amended, claim 36 is canceled and new claims 49-52 are added. In addition, submitted herewith are replacement formal drawings to replace all of the drawings of the original application. Reconsideration in view of the above amendment and the following remarks are respectfully requested.

The drawings were objected to under 37 CFR 1.84(p)(5) because they did not include reference number 6. By this Amendment, Applicant submits herewith three corrected sheets in which the missing reference number has been added to Figures 1, 3, 4a, 4b, 7 and 8.

Reconsideration and withdrawal of the drawing objection are respectfully requested.

On page 2, paragraphs 2 and 3, the Office Action objects to the Abstract. By this Amendment, the Abstract has been replaced to obviate the use of legal phraseology.

Reconsideration and withdrawal of the objection are respectfully requested.

Claims 32, 33, 39-42 and 43-48 were rejected under 35 U.S.C. §112, second paragraph. By this Amendment, claim 32 has been amended so as to eliminate reference to the operator. In addition, claim 32 has been amended to specify that the first hollow body has an edge that is comprised in a base of the first truncated-cone portion. As a result, claim 32 has been changed to depend from claim 29 instead of claim 27 for strict antecedent basis.

Reconsideration and withdrawal of the rejection are respectfully requested.

Claim 38 was objected to based on a typographical error which has been corrected by this Amendment.

Claims 25-36 and 38-45 were rejected under 35 U.S.C. §103(a) over Budding (U.S. Patent No. 5,464,412) in view of Kaji (U.S. Patent No. 6,142,931). This rejection is respectfully traversed.

At the outset, Applicant respectfully submits that Budding and Kaji are directed to mutually exclusive structures and therefore there is no motivation to combine the two. In particular, Budding is directed to a solo operated hemorrhoid ligator in which elastic rubber bands 10 are attached to hemorrhoid tissue of a patient. The elastic band 10 is affixed to a distal end of an inner barrel 6 upon insertion into an outer barrel 4. A loading mandrel 14 is used to load elastic band 10 onto the distal end of inner barrel 6. The device of Budding is specifically used for elastic band ligation of hemorrhoids, and Budding does not specify any other possible uses for this very specialized instrument. By contrast, Kaji is not specified for use in rubber band ligation and nor is it suited for such. Moreover, the device of Kaji is a much larger device and requires a viewing scope for use as it relates typically to deep tissue endoscopic surgery.

Thus, there is no reason why one of ordinary skill in the art would have combined the teachings of Budding and Kaji. Specifically, there is no reason why one of ordinary skill in the art would have provided Budding with an operating window (claim 25) or relatively rotatable hollow bodies (claims 25 and 27). Budding's rubber band ligation tool would simply not benefit in any way from adoption of Kaji's window or relative barrel rotation. Any suggestion to combine features of Kaji with Budding are provided solely by Applicant's own disclosure, which is not the proper basis for a *prima facie* case for obviousness.

In addition, the anoscope according to independent claims 25 and 27 enables a very effective surgical technique (hemorrhoidal dearterialization with transanal anopexy, or the "Sias"

method) to be carried out, which technique has been developed by the Applicant and owing to which hemorrhoids can be treated surgically on an outpatient basis and without anesthesia.

The Sias method is based on an anatomical feature, i.e., on the constant presence of six terminal arterial branches coming from the lower hemorrhoidal artery, which arterial branches are arranged along the wall of the rectum according to a precise geometry at the end of which hemorrhoids form. If a patient is arranged in a prone position, so that the anal opening of the patient is arranged frontally, the six arterial branches are placed on an imaginary clock face at 1, 3, 5, 7, 9 and 11 o'clock, respectively. Therefore, the surgeon can make a ligature of the six arterial branches, through the so-called "Z" suture, by intervening above the hemorrhoids. Further, the region of mucous membrane of the rectum that undergoes the operation substantially devoid of sensitive nerves, owing to which any local anesthesia becomes unnecessary.

Such an operation enables operating time to be halved, in comparison with other types of surgical treatment of hemorrhoids, and does not require the patient to be hospitalized. Nevertheless, according to this surgical technique, a plurality of sutures have to be carried out in preset positions of the rectal wall and the surgeon needs assistance to position the operating window of the anoscope precisely at the arterial branch that is to be sutured.

The anoscope defined in claims 25 and 27 enables this surgical technique to be carried out with precision and efficiency. Claim 25 specifies that the second hollow body is provided with the window arranged to make a portion of rectal mucous membrane accessible, the window comprising an operating window that has dimensions and the shape such as to enable a surgical device to intervene on the aforesaid portion. In this way, the operating window defines an area in which the surgeon can come in direct contact with the rectal mucous membrane and carry out the "Z" suture according to the above mentioned technique.

In regard to claim 27, neither Budding nor Kaji teaches or suggests that the reciprocal angular positions correspond to the same number of positions that can be taken up by the window. Figures 5a and 5b of Kaji clearly show that the treatment windows 31 and 32 comprised in sheets 3 and 4, respectively, are intended for suitably receiving a surgical tool. The windows can be rotated relative to one another such that they may be overlapped, not overlapped, or only partially overlapped. Moreover, no suggestion is given in Kaji in order to lock the inner sheath 4 in a preset position by acting on the first connector 6 and the second connector 25. In fact, the opening and/or closing of the treatment windows 31 and 32, i.e., the rotating of the inner sheath inside the outer sheath, is performed under visual control of the operator, which visual control is achieved through scope 37. Further, by abutting Budding's exterior barrel 4 with the first connector 6 of Kaji and abutting Budding's interior barrel 6 with the second connector 25 of Kaji, the interior barrel will become freely rotatable inside the exterior barrel 4, but no means would be provided in order to lock the interior barrel 6, and thus respective window in a preset position.

In addition, neither Budding nor Kaji teaches or suggests the subject matter of the dependent claims. For example, Budding does not teach the claimed second truncated cone portion (claims 30-31), especially as the Examiner has incorrectly identified a cylindrical portion as the second truncated cone.

As another example, claim 38 specifies that the window opens near to the point that can be reached by the tip of an index finger of a hand of an individual of medium build, by inserting the index finger inside the second hollow body. There is no teaching or disclosure that the devices of either Budding or Kaji include barrels that can accommodate the index finger of the performing surgeon. In any event, there is also no teaching or disclosure that the window of Kaji

is suitable for inserting the index finger, especially given that the window of Kaji has a variable size, the smallest of which is clearly not capable of receiving the index finger of the surgeon. Moreover, there is no teaching or suggestion to dimension increase the size of barrels 4 and 6 of Budding so as to allow the passage of the index finger of the surgeon. Again, Budding relates to rubber band ligation in which it is not necessary for the surgeon to insert his finger into the barrel. Rather, a tool such as forceps or a tenaculum is inserted into the barrel for pulling the effected tissue into the barrel such that the elastic band 10 may be applied around the hemorrhoid.

Reconsideration and withdrawal of the rejection are respectfully requested.

Claim 37 was rejected under 35 U.S.C. §103(a) over Budding in view of Kaji and further in view of Block (U.S. Patent No. 4,834,067) and claims 46-48 were rejected under 35 U.S.C. §103(a) over Budding in view of Kaji and further in view of Boebel (U.S. Patent No. 4,538,594). These rejections are respectfully traversed as claims 37 and 46-48 depend from or otherwise include the limitations of independent claims 25 or 27. In addition, Block discloses a speculum consisting of a single hollow body and Boebel discloses a rectoscope consisting of a single tube. Thus, Block and Boebel teach away from a device comprising two co-axially coupled hollowed bodies as recited in claims 25 and 27.

Reconsideration and withdrawal of the rejections are respectfully requested.

New claims 49-52 are presented for the Examiner's consideration.

In view of the above amendments and remarks, Applicant respectfully submits that all the claims are patentable and that the entire application is in condition for allowance.

The Commissioner is hereby authorized to charge any deficiency, or credit any overpayment, in the fee(s) filed, or asserted to be filed, or which should have been filed herewith

SIAS, Francesco
Appl. No. 10/527,133
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(or with any paper hereafter filed in this application by this firm) to our Account No. 14-1140
under Order No. PTB-4462-13.

Should the Examiner believe that anything further is desirable to place the application in
better condition for allowance, he is invited to contact the undersigned at the telephone number
listed below.

Respectfully submitted,

NIXON & VANDERHYE P.C.

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PTB:jck
Attachments:
Replacement Abstract
Replacement Figures 1-8 (3 sheets)

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